REMARKS

This is a full and timely response to the non-final Official Action mailed October 24, 2005. Reconsideration of the application in light of the following remarks is respectfully requested.

Claim Status:

Claims 1-28 are now pending for further action.

Claim Objection:

The recent Office Action objected to claim 21 due to a minor typographical error. That error has been corrected in the present paper. The amendment to claim 21 does not, and is not intended to, narrow or alter the scope of the claim. Following entry of this amendment, the objection to claim 21 should be reconsidered and withdrawn.

Prior Art:

The outstanding Office Action rejected claims 1-28 as anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,721,603 to Zabara et al. ("Zabara"). For at least the following reasons, this rejection is respectfully traversed.

Independent claim 18 recites: "A method of using an implantable electrical stimulator to treat angina pectoris, comprising electrically stimulating an intercostal nerve or intercostal nerve branch with an implanted stimulator so as to treat said angina pectoris."

In contrast, Zabara does not teach or suggest a method of using a stimulator to treat angina pectoris. Zabara does not even mention angina pectoris.

Angina pectoris is "a disease marked by brief paroxysmal attacks of chest pain precipitated by deficient oxygenation of the heart muscles." (Merriam-Webster Online Dictionary: http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=angina+pectoris). In contrast, Zabara teaches a "method of treating patients suffering from chronic or persistent pain of neuropathic, psychogenic or nociceptive origin or causation." (Zabara, claim 1). Zabara does not ever teach or suggest a method of treating angina pectoris which arises from deficient oxygenation of the heart muscles.

Additionally, Zabara does not clearly teach or suggest the stimulation of an intercostal nerve or intercostal nerve branch as claimed. Zabara does teach stimulating the vagus nerve. (Col. 3, lines 65 *et seq.*), and the vagus nerve does have intercostal branches. However, Zabara does not ever specifically teach or suggest stimulation of those portions of the vagus nerve that are intercostal and that could effect angina pectoris. The vagus nerve stimulated in the teachings of Zabara carries only *parasympathetic* fibers. In contrast, angina pectoris is thought to be associated with stimulated afferent cardiac pain fibres that predominantly ascend to the *sympathetic* ganglia (C7–T4) and synapse in the dorsal horn of the spinal cord along with other converging afferent nociceptive fibres. Thus, Zabara's stimulation of the vagus nerve would not appear to have any effect on angina pectoris.

The burden is on the Office to demonstrate how and where Zabara unequivocally teaches the claimed subject matter. *Ex parte Levy*, 17 U.S.P.Q.2d 1461 (BPAI 1990). In this case, the Office Action fails to indicate how or where Zabara specifically teaches stimulation of an intercostal nerve effective to treat angina pectoris.

Consequently, Zabara fails to teach or suggest any of the subject matter of claim 18. "A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Verdegaal Bros. v. Union Oil Co. of California, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least these reasons, the rejection of claim 18 and its dependent claims based on Zabara should be reconsidered and withdrawn.

Independent claim 28 recites:

> A method of using an implantable electrical stimulator to treat angina pectoris, comprising alleviating symptoms of said angina pectoris using said stimulator that applies electrical stimulation to any of an intercostal nerve, intercostal nerve branch, afferent fibers along cardiac sympathetic nerves, first through fourth thoracic sympathetic ganglia, stellate ganglia, afferent fibers along cardiac parasympathetic nerve fibers, superior cervical (vagal) cardiac nerve, interior cervical (vagal) cardiac nerve, thoracic cardiac branch of a patient's vagus nerve, parasympathetic ganglia or neurons lying in fat pads located next to a patient's sinoatrial node, atrioventricular node or ventricles, a sympathetic trunk at spinal levels T1 through T4, and sympathetic nerves in a patient's thorax, abdomen or pelvis.

As demonstrated above, Zabara fails to teach or suggest a method of using an implantable electrical stimulator to treat angina pectoris through the stimulation of an intercostal nerve. For at least these reasons, the rejection of claim 28 should be reconsidered and withdrawn. Moreover, Zabara also appears to fail to teach or suggest stimulating any of the specific stimulation sites recited in claim 28.

In this regard, the recent Office Action cited to Zabara at col. 3, lines 40-65. (Action of 10/24/05, p. 6). However, this portion of Zabara teaches the stimulation of "cranial nerves," specifically the trigeminal nerve (col. 3, lines 50-64) and the vagus nerve (col. 3, lines 65 *et seq.*). No where does Zabara teach or suggest stimulating any of the specific sites recited in claim 28, and/or the recent Office Action has failed to explain how or where the teachings of Zabara are read on by claim 28.

Again, "[a] claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single

prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least these reasons, the rejection of claim 28 based on Zabara should be reconsidered and withdrawn.

Independent claim 1 recites:

> A method for treating a patient with angina pectoris, comprising:
> providing a miniature leadless implantable stimulator with at least one electrode and with a size and shape suitable for placement of the entire stimulator adjacent to a nerve;
> implanting the stimulator adjacent to at least one tissue influencing the angina pectoris of the patient, which tissue is at least one of an intercostal nerve and an intercostal nerve branch;
> providing operating power to the stimulator;
> using an external appliance to transmit stimulation parameters to the stimulator;
> receiving the stimulation parameters at the stimulator;
> generating stimulation pulses in accordance with the stimulation parameters, which pulses are generated by the stimulator;
> delivering stimulation pulses via the stimulator to the at least one of the intercostal nerves and intercostal nerve branches influencing angina pectoris as a treatment for angina pectoris.

(emphasis added).

As demonstrated above, Zabara fails to teach or suggest a method of treating a patient with angina pectoris or stimulating an intercostal nerve to effect such treatment. For at least these reasons, the rejection of claim 1 and its dependent claims should be reconsidered and withdrawn.

Moreover, Zabara also fails to teach or suggest "providing a miniature leadless implantable stimulator with at least one electrode and with a size and shape suitable for placement of the entire stimulator adjacent to a nerve." In this regard, the Office Action cites to Zabara at col. 4, lines 24-28. (Action of 10/24/05, p. 2). This portion of Zabara reads as follows:

> To provide the therapy, a medical interventional device is implanted in the patient at a position in the chest or the abdomen selected to accommodate the patient's cosmetic desires as well as to be positioned within a region accessible to the designated nerve. The implanted device responds to activation to generate an electrical signal whose parameters are predetermined to deliver the desired therapy to the patient to alleviate or mask the pain. To that end, an electrode at the distal end of an electrical lead is implanted in stimulating and sensing relation onto the designated nerve

Thus, Zabara teaches a device that is implanted to "accommodate the patient's cosmetic desires" with "an electrode at the distal end of an electrical lead [that] is implanted in stimulating and sensing relation onto the designated nerve." Moreover, as illustrated in all the figures of Zabara, a generator (1) is implanted at a distance from the nerve to be stimulated. Lead (2) then runs between the generator (1) and the cuff electrodes (21, 22) on the nerve(s) to be stimulated. Zabara most certainly does not teach or suggest "providing a miniature *leadless* implantable stimulator with at least one electrode and with a size and shape suitable for placement of the entire stimulator adjacent to a nerve." (emphasis added).

Again, "[a] claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least these reasons, the rejection of claim 1 and its dependent claims based on Zabara should be reconsidered and withdrawn.

Independent claim 9 recites:

> A method for treating a patient with angina pectoris, comprising:
> providing a miniature implantable stimulator with at least one electrode and with a size and shape suitable for placement of the at least one electrode adjacent to a nerve;
> implanting the at least one electrode near at least one tissue influencing the angina pectoris of the patient, which tissue is at least one of an intercostal nerve and an intercostal nerve branch;

providing operating power to the stimulator;
using an external appliance to transmit stimulation parameters to the stimulator;
receiving the stimulation parameters at the stimulator;
generating stimulation pulses in accordance with the stimulation parameters, which pulses are generated by the stimulator;
delivering stimulation pulses via the stimulator and the at least one electrode to the at least one of the intercostal nerves and intercostal nerve branches influencing angina pectoris as a treatment for angina pectoris.

(emphasis added).

As demonstrated above, Zabara fails to teach or suggest a method of treating a patient with angina pectoris or stimulating an intercostal nerve. For at least these reasons, and the other reasons given above with respect to the other independent claims, the rejection of claim 9 and its dependent claims should be reconsidered and withdrawn.

Additionally, the various dependent claims of the present application recite further subject matter that is neither taught nor suggested by the prior art of record, particularly Zabara. Specific examples follow, and, for at least these additional reasons, the rejection of these claims should be further reconsidered and withdrawn.

Claim 3 recites "generating and delivering stimulation pulses of less than about 15 mA to at least one of the intercostal nerves and the intercostal nerve branches." Claim 12 recites similar subject matter. The recent Office Action fails to indicate how or where Zabara teaches or suggests this subject matter.

Claim 4 and 5 recite, respectively, that "the implantable stimulator further comprises at least one sensor and the method further comprises sensing at least one condition of the patient," "wherein the at least one sensed condition is used to adjust the stimulation parameters." Claims 8, 13-17 and 20 recites similar subject matter. In contrast, Zabara teaches a sensor that is only used to sense when a patient is experience pain and accordingly

trigger the activation of the implanted device." (Zabara, col. 4, lines 46-51). However, Zabara does not teach or suggest that stimulation parameters are adjusted using a sensor outputting a sensed condition of the patient, as claimed.

Claim 21 recites that the condition sensed is "any of blood oxygen level, electrical activity of the patient's heart, patient activity level, respiratory rate, medication level, neurotransmitter level, hormone level, interleukin level, cytokine level, lymphokine level, chemokine level, growth factor level and enzyme level." Zabara does not teach or suggest a sensor sensing any of these specific conditions.

Claim 19 recites "wherein said stimulator is a self-contained unit that is sized and shaped for placement of the entire stimulator adjacent to a nerve, said method further comprising implanting said entire stimulator adjacent said intercostal nerve or intercostal nerve branch." Again, as indicated above, Zabara fails to teach or suggest this subject matter.

Claim 23 recites, "after applying said series of inhibitory electrical stimulation pulses, sensing any change in sympathetic firing rate and adjusting electrical stimulation applied with said implanted stimulator in response to any sensed change in sympathetic firing rate." Zabara fails to teach or suggest this subject matter. The recent Action fails to indicate how or where Zabara teaches such subject matter.

Conclusion:

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper, that have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

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